

REMARKS

This communication is in response to the outstanding Restriction Requirement mailed August 5, 2005, in the above-identified application, having a one-month period for response set to expire September 5, 2005. Reconsideration and allowance of the above-identified patent application are respectfully requested. Please credit any overpayment or charge any fee deficiency to Deposit Account No. 13-2755.

The claims are amended herein. Claims 1-36 are currently pending.

Claims 22-24 were objected to on the basis that the appropriate claim dependency was not clear. Applicants respectfully traverse. Claims 22-24 are cancelled herein, without prejudice. Applicants submit current claims 34-36 sufficiently cover the subject matter of the cancelled claims. Accordingly, Applicants respectfully request reconsideration and withdrawal of the objection.

Claims 18, 31, and 34-36 are amended herein.

Claims 18 and 31 are amended with support found, *inter alia*, at pages 12-13 and generally throughout the application. Claims 18-19 and 31-32 were rejected under 35 U.S.C. §112, second paragraph and, as a result thereof, were withdrawn from the imposed election restriction. The claims were said to omit an essential step, namely, where the composition would be administered (*e.g.*, to a cell *in vitro* or to an individual). Applicants respectfully traverse. Claims 18-19 and 31-32 particularly point out and distinctly claim administration methods for eliciting an enhanced immune response through described prime-boost protocols. One of skill in the art, upon reading the specification, would clearly recognize this claim as defining a means to elicit an enhanced immune response in a subject of interest as described in greater detail in the specification. In efforts to advance prosecution on the merits, however, Applicants have amended claims 18 and 31, and thereby (through dependency), claims 31-32, to import specific language indicating that administration of the composition and associated administrations would be delivered *in vivo*. Accordingly, Applicants respectfully request reconsideration and withdrawal of the rejection.

Applicants await instructions in future correspondence as to where the amended claims are seen to fit within the current restriction scheme.

Claims 34-36 are amended to better conform the language therein with that of the antecedent claims to which they depend. Support can be found, *inter alia*, at page 10 of the specification.

Presuming amendment of the application in accordance with the instant request, Claims 1-21 and 25-36 will be pending. No new matter has been added.

Restriction

The Restriction Requirement sets forth the following inventions or groups of inventions which are stated to be distinct from each other:

- Group I: Claims 1-17, 20, 22-30 and 34-36, drawn to an adenovirus comprising a recombinant adenoviral vector of serotype 34, wherein at least part of the E1 region is deleted, and methods of producing the recombinant adenovirus, classifiable in class 435, subclass 320.1.
- Group II: Claims 21 and 33, drawn to a method of generating a cellular-mediated immune response in an individual comprising administering an adenovirus comprising an HIV gene, classifiable in class 424, subclass 93.2.

The Restriction Requirement, furthermore, sets forth a requirement that Applicants elect a single group to which the claims must be restricted.

Applicants respectfully traverse herein the Restriction Requirement. Given the degree of relation amongst all the claims due to the fact that they all relate to the use of recombinant, replication-defective adenovirus serotype 34 vectors, Applicants submit that it should not be an undue burden for the Examiner to evaluate Applicants' specification in its entirety. Where a search and examination of an entire application can be made without a serious burden, MPEP 803 dictates that all claims should be examined on the merits.

Applicants, thus, respectfully submit that it is not proper to restrict claims 1-21 and 25-36 into separate applications.

To be fully responsive, however, Applicants hereby elect Group I, now claims 1-17, 20, 25-30, and 34-36, without prejudice to the prosecution of non-elected claims in related continuation or divisional patent applications.

Election of Species

In accordance with the Restriction Requirement, Applicants are required to elect a single disclosed species within the elected Group (designated above as Group I, now claims 1-17, 20, 25-30, and 34-36) to which claims would be restricted if no generic claim is finally held to be allowable. The application, it is stated, contains claims directed to the following allegedly patentably distinct species of the claimed invention: HIV antigen selected from HIV-1 gag, HIV-1 nef, HIV-1 pol, or an HIV antigen selected from page 10, lines 31-32 (gp160, gp41, gp120, tat, rev and derivatives thereof).

Applicants respectfully traverse the requirement for election of species.

In order to advance prosecution on the merits, however, and to fully comply with the requirement for election, Applicants herein designate HIV-1 gag as the species within Group I for examination on the merits. Claims 20 and 25-29 are indicated as generic claims encompassing HIV-1 gag within their scope. Applicants submit that claims 20 and 25-30 are generic to, and encompass, *inter alia*, HIV-1 gag within their scope. Additionally, claim 34 specifically recites a composition wherein the HIV-1 gene is HIV-1 gag.

Applicants submit that the above election of species is being made with the understanding that the election requirement will be withdrawn upon making a determination that an allowable generic claim exists.

Summary

Applicants respectfully request the reconsideration and withdrawal of the requirement for restriction. It is Applicants' position that claims 1-36 could properly be examined together.

Applicants respectfully submit that all claims are in condition for allowance and earnestly solicit a favorable action on the merits.

Please note that the Examiner is invited to contact the undersigned attorney at the telephone number provided below if such would advance the prosecution of the case.

Respectfully submitted,

By



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